Is the Standard of Care What We Think It Is?

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ABSTRACT

For the most part, gynecologists are actually unaware of the issues involving surrogate versus quality of life outcomes, the "deceptive practice of medicine" and the true incidence of complications as they relate to the standard of care. An anonymous survey of 1958 practicing gynecologists attending seven national symposia revealed a significant number of unreported complications. Clearly, the standard of care (at least with regard to complication risk) is markedly different than has been suggested by the medical literature. Concomitantly, we suggest that physicians need to take a more active role in the policing of our own specialties.

Key Words: Standard of care, Complications, Laparoscopy, Gynecology, Outcomes.

DISCUSSION

Most gynecologists seem to function under the assumption that they practice medicine within the standard of care for their hospital or community. But the average gynecologist probably does not think about the standard of care until he or she is required to define the term on the occasion of a lawsuit. In the legal sense, the term "standard of care" refers to the fact that it is expected that the physician should bring to the practice the reasonable degree of care and skill possessed and exercised by others in the school or system of practice of medicine that the physician follows in the locality in which the physician practices, or in similar localities.

Thus, the standard can be divided into three components: 1) the reasonable degree of care and skill possessed and exercised by other physicians, 2) the school or system of practice that the physician follows, and 3) the locality in which the physician practices. In reality, at the present time, the first portion of the statement remains constant and agreed to by most academics. The second portion has become relatively unimportant as the allopathic and homeopathic schools of medicine have been combined. The third portion, on the other hand, remains in a state of transition as arguments persist regarding dissimilarities between practice patterns around the United States.

To our minds, the definition of the term "standard of care" should be in some manner outcome based. That is to say, the term should be defined as the care provided to a patient at a particular period of time for a particular problem relevant to a specific outcome. There are, essentially, only two potential outcomes: a surrogate outcome and a quality of life outcome. For example, a surrogate outcome for an infertility patient might be a positive pregnancy test. The truth is that the patient does not really care about the surrogate outcome, in this case the positive pregnancy test. She is concerned only about the quality of life outcome, having a baby. Therefore, a positive pregnancy test that is associated with a miscarriage or an ectopic pregnancy is no longer considered a success.

Along this same line of discussion, what if that same

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infertility patient asked you about your success rate in the management of patients with similar problems? The first words out of your mouth might be. "Well, I've cared for many patients with problems similar to yours." If she then asks you for the percentage of time that your similar patients have been successful and you tell her some number, you had better be right! If not, you may well have entered into the "Deceptive Practice of Medicine." The very same issues exist if you are talking to a patient about a potential surgical procedure and she questions you about the risk of complications. What are your risks? If you quote a figure that is representative of the "standard" in the community, you hold yourself out to be similar to the other physicians who practice in your hospital, your community, or perhaps in the United States. The question must remain, however, whether the risks of complications attendant with a given procedure performed by you are the same, less or more than those associated with the standard of care as it has been defined.

It is very difficult to define the incidence of complications as they exist under the standard of care concept. For the most part, it is extremely unusual for individual physicians to maintain an accurate database of procedures performed by diagnosis, outcomes, and complications. Indeed, when attempting to define the incidence of complications associated with the standard of practice, one must go to the published medical literature where one finds out-of-date information collected from individual or limited practices of experts from which it is necessary to extrapolate results.

The true rates of complications associated with gynecologic surgery really are not known. This remains a correct statement in spite of the efforts of a number of organizations over the past several years. Perhaps the most courageous endeavor in this regard is that of the membership survey of the American Association of Gynecological Laparoscopy (AAGL). Nonetheless, while coming closer to achieving reliable results than perhaps any other previously undertaken survey, this survey has numerous shortcomings, which make it of limited value when attempting to speak realistically to one's patients. Virtually no physicians keep accurate records of the total number of procedures that they actually perform over time. Nor do they keep track of indications, diagnoses and, most importantly, complications.

The AAGL, as previously stated, has attempted to gather information on complications associated with endoscopic surgery and has published the results of their surveys on several occasions.[1,2] Importantly, as we review these data, we recognize that the surveys must be based largely on recalled data since it is our belief that very few gynecologists actually have database information upon which to respond to this sort of survey. Furthermore, in reviewing the medical literature, we find a paucity of data regarding actual complication rates.[3-14] This lack of data holds important ramifications for the issue of defining a standard of care, for the issue of appropriate and accurate counseling of patients in a preoperative setting and, obviously, for the issue of a medical-legal argument.

During the course of seven national symposia, sponsored by Medical Education Collaborative through an unrestricted educational grant from TAP Holdings, Inc., we have had the opportunity to address, at least partially, the issue of incidence of complications during laparoscopic surgical procedures. These seven symposia were attended by 1958 practicing physicians. At each symposium, an interactive computer system (the IRIS system) was utilized to collect physician responses to questions posed by the speakers. The IRIS system includes a telephone key pad at each attendee's seat and allows each attendee to respond to questions anonymously. Moreover, the IRIS system allows for almost instantaneous compilation of results and presentation of the results back to the audience in a variety of visual formats. Thus, numerous questions concerning the performance of various surgical procedures were posed, and responses were accumulated over the course of the seven separate symposia. We subsequently have had the opportunity to acquire the compiled data, which we present below.

We recognize that there remain some significant potential biases even with the use of the IRIS system. Respondents were asked to recall information anecdotally without data at their fingertips. Thus, a question such as "How many laparoscopic procedures do you perform per week?" might be open to significant recall bias. On the other hand, questions such as "Have you ever had a ureteral injury?" were more likely to receive unbiased results since the responses were anonymous, and, in our experience, most surgeons can recall if they have ever been involved with a given type of complication. Indeed, most surgeons recall complications only too well. Of course, the bias remains regarding respondents who answer affirmatively despite actually never having had such a complication.

The results of these surveys are staggering and are presented in **Tables 1-4**. The incidence of each complication (herein presented as the number of respondents answering that they had experienced at least one such complication) is presented. Because of the manner in which the questions were posed, an affirmative response that the surgeon had experienced such a complication may underestimate the true incidence of said complication, since a given surgeon may actually have experienced more than one such complication. In addition, we present data regarding the instrument believed to be involved in the complication as well as the type of surgical procedure being performed when the complication occurred.

From the results of this survey, we conclude that the true incidence of complications associated with laparoscopic surgery is probably grossly underestimated in the published literature. For example, through 1990, there were only 13 laparoscopic ureteral injuries reported in the English language literature.[15] From the results of this survey of 1958 physicians, we found that at least 74 ureteral injuries had occurred (which, as mentioned, may represent an understatement of the actual number). In this case, ureteral injury represented 3.8% of the complications that were observed. This does not represent the rate per thousand laparoscopies but only the total number of unreported injuries in this group of physicians.

We learned some other interesting information from this process. Over 30% of the physicians surveyed admitted to performing frequent laparoscopies in which either no abnormality is noted or disease is considered too severe to be managed by the laparoscopic route. Based on the number of laparoscopic procedures performed by this group of physicians, we have attempted to estimate the

Table 1.[1]
Incidence of Laparoscopic Complications.

Complications	Rate
Pneumoperitoneum	0.7
Bleeding	0.6
Perforating injuries	0.4
Infection	0.1
Intestinal injury	0.05
Cardiac Arrest	0.03

Table 2.
Incidence of Laparoscopic Complications.

Bleeding trocar site	892	45.6%
Major vessel	99	5.0%
Ureter injury	74	3.8%
Bowel injury	343	17.5%
Bladder injury	172	8.8%
None	378	19.3%

Table 3.
Modality Responsible for Injury.

	Major Vessels	Ureter	Bowel	Bladder
Monopolar cautery	3.2%	10%	20.5%	29.6%
Bipolar cautery	1.6%	20%	17.9%	11.1%
CO_2 Laser	1.6%	0	2.6%	0
Argon Laser	1.6%	0	2.6%	3.7%
Yag Laser	1.6%	0	2.6%	0
Endo-GIA stapler	6.5%	20%	2.6%	0
Trocar	59.7%	0	10.8%	40.7%
Veress needle	14.5%	10%	10.3%	3.7%
Don't know	9.7%	40%	10.3%	11.1%

Table 4.
Procedure Where Injury Occurred.

	Range
LAVH	21.1%-22.8%
Unilateral SO or BSO	10.7%-15.8%
Endometriosis surgery	7.9%-9.4%
Adhesiolysis	13.2%-16.3%
Myomectomy	0%-0.9%
Ectopic pregnancy	3.9%-5.5%
Neosalpingostomy	0%-0%
LUNA procedure	1.3%-0%
Presacral neurectomy	0%-0%
Tubal ligation	6.6%-26.7%
Diagnostic laparoscopy	18.4%-30.3%

economic impact of these "non-productive" laparoscopic procedures. It is recognized that there are some 34,000 practicing gynecologists in the United States. From our survey, we estimate that approximately 20,000 of these gynecologists perform laparoscopy. Again, from our survey, we found that the average physician performs approximately four cases per month. If 30% are "non-productive," that would be approximately 15 subsequent additional surgeries. This would translate to 288,000 non-productive laparoscopic procedures per year. At an average total cost of $5000, that would mean that the cost for "non-productive" laparoscopies approaches $1,440,000,000 per year.

Only 50% of the attendees had actually attended "hands on" courses to learn the techniques of laparoscopic surgery. The rest just started performing the procedures. We could not determine whether injuries occurred more commonly at the hands of surgeons with no formal training.

So what does all of this mean? We believe that a number of significant issues come to light. Clearly, the standard of care (at least with regard to complication rate) is a lot different than has been suggested by the medical literature. From the medical legal standpoint, the actual incidence of complications among reasonable and skilled practitioners is much higher than has been documented previously. It also points to the fact that physicians need to take a more active role in the policing of our own specialties. Can you imagine any other technical field in which it would be acceptable for the practitioner to "just start" performing the technical feat without some formal training? How about flying a plane? Or driving a taxi? It is incumbent upon the physicians who practice at each institution to ensure that adequate credentialing occurs. This does not mean that those who get the training first have a right to preclude newcomers from the field. Indeed, we believe that it is the obligation of those with the skill to ensure that all who practice our specialty have the opportunity to gain the skills needed to deliver the best care to our patients. In that way, we serve as true advocates for our patients.

We recognize that there are limits to the interpretation given to the results we present. Clearly the potential for bias does exist. However, the fact remains that the incidence of complications in practice is higher than what is reported in the literature.

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